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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FUELLING, MICHAEL

ART UNIT	PAPER NUMBER
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3626

NOTIFICATION DATE	DELIVERY MODE
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11/10/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/589,560	Applicant(s) ABRAHAM-FUCHS ET AL.	
	Examiner MICHAEL FUELLING	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/19/2009 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This is a Final Office Action for Application Number 10/589,560 filed August 16, 2006.

Claims 1-23 have been amended and examined.

Priority

The examiner raised the issue of whether the applicant had perfected its claim to priority, and the applicant did not appear to respond. Nonetheless, this issue is not being reiterated, in as much as no allowable subject matter has been identified.

Drawings

In view of the amendments to the system claims, the drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the first data network of claims 7 and 17, and the second data network of claims 9 and 19, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet"

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pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Response to Amendment

The 35 USC 112, first paragraph, claim rejections are withdrawn, however, applicant's amendments are insufficient to place this case in a condition for allowance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 7 and 17 recite "limited access". Applicant's written description is devoid of such term, so it is unclear how access is limited. Claims 2-6, 8-16 and 18-23 have the same defect through dependency. It is being interpreted access to the network(s) and data is restricted.

Claims 1, 7 and 17 recite "limited access" and "the access". It is unclear whether these are the same access. Claims 2-6, 8-16 and 18-23 have the same defect through dependency. It is being interpreted they are the same access.

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Claims 8 and 18 recite the memory is portable. It is unclear whether this is different than the portability recited in claims 7 and 17. Claim 15 has the same defect through dependency. It is being interpreted this is the same portability.

Claims 9 and 19 recite another network. It is unclear whether this is different than the network recited in claims 7 and 17. Claim 16 has the same defect through dependency. It is being interpreted the portable device could be part of more than one network.

Claims 9 and 19 recite another authorization. It is unclear whether this is different than the authorization recited in claims 7 and 17. Claim 16 has the same defect through dependency. It is being interpreted the system could use more than one security means.

Claim 17 recites "memory means" and "the memory". It is unclear whether this is the same memory. Claims 18-20 have the same defect through dependency. It is being interpreted this is the same memory.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brimm et al., US Patent Number 5,072,383 (Brimm) in view of Brown, US Patent No. 6,168,563 (Brown)

Referring to claims 1, 7 and 17, Brimm discloses a method and system, including a computer memory (C4, L24), the method comprising:

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- *storing data associated with a protocol of a medical regimen* (C4, L10-20 “automated clinical records management”)
- *storing patient-related data associated with the patient and the medical regimen* (Abstract patient information system)
- *reading by a computer associated with another doctor assigned to the patient the data* (Abstract physician and C4, L25 terminal unit with display means)

While Brimm does not appear to expressly use the term “clinical study”, Brimm discloses a medical regimen, as detailed above, and a clinical study is a medical regimen. Further, applicant’s use of the term “clinical study” merely is a nonfunctional description of the data. Nonfunctional descriptive material cannot render nonobvious in an invention that would have otherwise been obvious. *In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004). *Cf. In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability).

Claims 1, 7 and 17 recite is / being “one of (1) a portable memory device transported by the patient and (2) part of a data network with limited access, the access being authorized by the patient” (emphasis added). The examiner described in the previous rejection the “* * * is one of a * * * and part of a * * *” phrase was vague and indefinite, and applicant’s insertion of the numbers (1) and (2) will be accepted as a bona fide attempt to respond. It is being interpreted both (1) and (2) are required because the phrase “at least” does not precede “one of” and applicant’s remarks state the above recitation is a limitation (p. 11). Further, (1) and (2) aren’t mutually exclusive conditions, so both features could exist at the same time in both i) one or more embodiments of the method, and ii) one or more embodiments of the system.

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Brimm does not appear to expressly disclose a portable memory device transported by the patient, which is a part of a data network, with "limited access" authorized by the patient.

Brown discloses such a device (Abstract – apparatus is operated by the patient; Figs. 2 & 3 and 31 & 32 – networks). The networked portable device (**2026**) has a memory (**2080**). Applicant described the way they grant access is by a patient physically giving their family doctor a USB [0054]. The examiner finds the way the device of Brown operates fairly reads upon applicant's claimed "limited access" because the device of Brown is controlled by the patient, thereby the patient decides whether another doctor may view the data which was placed on the device's memory by a first doctor (C29, L40 and C32, L35 - script programs).

Since each individual element and its function are shown in the prior art, albeit in separate references, the differences between the claimed subject matter and the prior art rests not on any individual element or function but in the very combination itself.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Brimm to substitute the portable memory device of Brown for the memory of Brimm, and the results would have been predictable.

Referring to claim 2, Brimm and Brown disclose all of the limitations of claim 1, and Brimm further discloses: *data is stored in the memory by a study doctor* (C9, L17 physician enters orders).

Alternatively, Brown discloses data is stored in the memory by a study doctor, as detailed above (C29, L40 and C32, L35 - script programs).

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It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Brimm to substitute the portable memory device of Brown for the memory of Brimm, and the results would have been predictable.

Referring to claims 3 and 11, Brimm and Brown disclose all of the limitations of claims 1 and 2, respectively, and Brimm further discloses: *another doctor reads the data out from the memory before an interaction with the patient* (C5, L53).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Brimm to substitute the portable memory device of Brown for the memory of Brimm, and the results would have been predictable.

Referring to claims 4 and 12, Brimm and Brown disclose all of the limitations of claims 1 and 2, respectively, and Brimm further discloses: *data is stored in the memory with standardized structuring* (Fig. 10).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Brimm to substitute the portable memory device of Brown for the memory of Brimm, and the results would have been predictable.

Referring to claims 5 and 13, Brimm and Brown disclose all of the limitations of claims 1 and 2, respectively, and Brimm further discloses: *clear instructions to another doctor are stored as data* (C11, L25 creation of task list).

Referring to claims 6 and 14, Brimm and Brown disclose all of the limitations of claims 1 and 2, respectively, and Brimm further discloses: *data is assigned to various*

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classes, and another doctor reads only information of one class out from the memory (C9, L19 select from a list the type of information).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Brimm to substitute the portable memory device of Brown for the memory of Brimm, and the results would have been predictable.

Referring to claims 8 and 18, Brimm and Brown disclose all of the limitations of claims 7 and 17, respectively, and the memory of Brown is portable, as detailed above.

The portable device (**2026**) has a memory (**2080**).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Brimm to substitute the portable memory device of Brown for the memory of Brimm, and the results would have been predictable.

Referring to claims 9 and 19, Brimm and Brown disclose all of the limitations of claims 7 and 17, respectively, and Brimm further discloses: *data input and output devices are connectable (C6, L18 monitoring equipment) and wherein authorization is required for access to the data (C9, L13 entry to the system restricted by security measures).*

Alternatively, to the extent it can be shown the input and output devices of Brimm would not interface with the portable device of Brown, Brown discloses input and output devices (Fig. 15 **2090** I/O interface, **2028** monitoring device).

It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the invention of Brimm, as modified by Brown, to substitute

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the input and output devices of Brown for such devices of Brimm, and the results would have been predictable.

Further, to the extent these claims are intended to be directed to more than one network, Brown discloses its portable devices are connected to more than one network (Figs. 2 & 3 and 31 & 32).

It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the invention of Brimm, as modified by Brown, to include the multiple networks of Brown, and the results would have been predictable.

Referring to claims 10, 15, 16 and 20, Brimm and Brown disclose all of the limitations of claims 7, 8, 9 and 17, respectively, and Brimm further discloses: *the data reading device is portable (11 bedside workstation)*.

Alternatively, to the extent it can be shown the reading device of Brimm would not interface with the portable device of Brown, Brown discloses a reading device on the portable device (Fig. 15 **2064** display).

It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the invention of Brimm, as modified by Brown, to substitute the portable memory and reading device(s) of Brown for such devices of Brimm, and the results would have been predictable.

Referring to claim 21, Brimm and Brown disclose all of the limitations of claim 1 and Brimm further discloses: *another doctor is a doctor who is at least one of not associated to the clinical study and external to the clinical study (Abstract physician)*.

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Referring to claim 22, Brimm and Brown disclose all of the limitations of claim 1 and Brimm further discloses: *the clinical study is conducted to test at least one of medicaments, methods of surgical intervention, therapies, and diagnostic devices* (C6, L19 such as a respiratory monitor; **8 10** bedside devices).

Referring to claim 23, Brimm and Brown disclose all of the limitations of claim 1 and Brimm further discloses: *displaying, by the computer, at least one of the study-related and the patient-related data to another doctor device* (C4, L25 terminal unit with display means).

Response to Arguments

Applicant's arguments received October 13, 2010 have been fully considered, but they are not persuasive, and are further moot in view of the new grounds of rejection.

Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a non-study doctor choosing a different drug) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Fuelling whose telephone number is (571)270-1367. The examiner can normally be reached on Monday - Friday, 8:30 am - 5 pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Morgan can be reached on (571)272-6773. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M.F./

Examiner, Art Unit 3626

/C. Luke Gilligan/

Primary Examiner, Art Unit 3626